STATE OF COLORADO

STATE BOARD OF PHARMACY
W. KENT MOUNT, Program Administrator
1560 Broadway, Suite 1310
Denver, Colorado 80202-5146
Telephone (303) 894-7750, FAX: (303) 894-7764
V/TDD (303) 894-7880

Department of Regulatory Agencies
Joseph A. Garcia
Executive Director

Division of Registrations
Bruce M. Douglas, Director

Roy Romer
Governor

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September 29, 1998

Thomas J. McGinnis, RPh
Deputy Associate Commissioner for Health Affairs
Office of Health Affairs
Food and Drug Administration
5600 Fisher Lane, Room 15A-08
Rockville, MD 20857

Dear Mr. McGinnis:

At its meeting on September 3, 1998, the Colorado Board of Pharmacy reviewed and considered various documents relating to compounding pharmacies and the Food and Drug Administration (FDA) Modernization Act of 1997. The documentation included requests from compounding pharmacists asking the Board to adopt a Memorandum of Understanding ("MOU") with the Food and Drug Administration (FDA), proposed by the Board's ad hoc task force. The Board also reviewed a proposed Memorandum of Understanding (MOU) between the Board and the FDA, a memorandum from the Board's Inspectors, correspondence from State Representative Marcy Morrison and a copy of a letter to the FDA from U.S. Senator Wayne Allard.

On behalf of the Colorado State Board of Pharmacy, enclosed is a proposed Memorandum of Understanding (MOU) for acceptance by the Food and Drug Administration (FDA). The Board believes the MOU is responsive to the requirements of Section 127, "Pharmacy Compounding" of the Food and Drug Modernization Act of 1997, by addressing specific compounded drug issues in Colorado.

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The Board understands there is a national task force meeting in October, for the purpose of attempting to consider drafting a single MOU that can be endorsed by

the National Association of Boards of Pharmacy and accepted by the FDA. The Colorado Board would consider withdrawing its proposed MOU when and if a suitable "national" MOU has been put in place via NABP.

The Board looks forward to your reply.

Please let me know if there is a question.

Sincerely,

FOR THE BOARD OF PHARMACY

W. Kent Mount
Program Administrator

Enclosure

Xc: Carmen A. Catizone, NABP
Elizabeth E. Hiner, RPh, FDA
State Representative Marcy Morrison
Tom Bader, RPh

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MEMORANDUM OF UNDERSTANDING

BETWEEN
THE COLORADO STATE BOARD OF PHARMACY
AND
THE FOOD AND DRUG ADMINISTRATION

I. INTRODUCTION

Pursuant to Section 127 of the Food and Drug Administration Modernization Act of 1997, "Pharmacy Compounding", the Colorado State Board of Pharmacy has developed this memorandum of understanding (MOU) with the United States Food and Drug Administration to address specific issues related to compounded drugs.

II. INVESTIGATION OF COMPLAINTS WITH RESPECT TO COMPOUNDED DRUGS SHIPPED OUT-OF-STATE

In general, the Board of Pharmacy in the state in which the compounding prescription drug outlet is located will investigate complaints about compounded drugs that are shipped out of the state. The Board may obtain the assistance of the Board that is located in the state where the compounded drug was shipped. If a complaint is received, either Board (in the state where the drug was shipped or the state where the compounding prescription drug outlet is located), may initiate the investigation. The Boards will, to the extent practicable, coordinate to determine which Board will investigate the complaint. The results of any investigation of a complaint may be shared with the other Board.

III. INORDINATE DISTRIBUTION OF COMPOUNDED DRUGS OUT-OF-STATE

A prescription drug outlet ("PDO") may dispense prescription orders for compounded drugs to be shipped interstate in an amount greater than 5% of its total prescription orders dispensed during the same calendar year. The PDO shall comply with all applicable state and federal laws, rules and regulations, including out-of-state registration/licensure and other applicable requirements which may be imposed by other states.

For the Colorado State Board of Pharmacy

W. Kent Mount
Program Administrator

DATED THIS 29TH DAY OF SEPTEMBER, 1998

For the Food and Drug Administration

Thomas J. McGinnis, RPh
Deputy Associate Commissioner for Health Affairs
Office of Health Affairs
Food and Drug Administration

DATED THIS ___ DAY OF_____, 1998